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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,375	08/17/2001	Matthew L. Warman	38464-0004	1602

26633 7590 07/21/2003

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EXAMINER
KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/21/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/931,375	Applicant(s) WARMAN ET AL.	
	Examiner Kathleen M Kerr	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

1. Claims 1-36 are pending in the instant application. Please note, claims beginning on page 81 were misnumbered as originally filed (two Claim 25's). Thus, Claims on pages 81-82 have been renumbered Claims 26-36.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-5, drawn to nucleic acid molecules and expression vectors related to SEQ ID NO:1, classified in class 435, subclass 320.1.

II. Claims 6 and 14, drawn to methods for modulating bone density using DNA, classified in class 800, subclass 13.

III. Claim 7, drawn to methods of using a vector to express a BSMR protein for selection of a test ligand that modulates bone density, classified in class 435, subclass 6.

IV. Claims 8-9 and 30-36, drawn to methods of regulating bone strength and mineralization by activating a bone density regulating transmembrane receptor and methods of treating osteoporosis, both using a ligand to BSMR, classified in class 514, subclass 12.

V. Claim 10, drawn to methods for determining bone strength and mineralization predisposition of a patient using nucleic acids and hybridization techniques classified in class 435, subclass 6.

VI. Claims 11-13, drawn to methods for determining bone strength and mineralization predisposition from analysis of epitopes on the bone strength and mineralization regulator protein, classified in class 435, subclass 7.21.

VII. Claims 15-17, drawn to methods of regulating bone strength and mineralization in a human subject using a protease, classified in class 424, subclass 94.63.

VIII. Claim 18, drawn to a portion of a bone strength and mineralization regulator protein, classified in class 530, subclass 350.

IX. Claims 19-21, drawn to methods for discovering a pharmaceutical useful for regulating bone strength or mineralization by noting binding between a BSMR protein and a test compound, classified in class 435, subclass 7.1.

X. Claims 22-29, drawn to compositions that improve bone strength and mineralization comprising a BSMR effector, classified in class 514, subclass 12.

3. The inventions are distinct, each from the other because of the following reasons:

Group I is related to Groups II, III, and V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the DNA of Group I can be used for a materially different process of using the product, such as in the recombinant production of the BSMR protein in *E. coli*. Thus, Group I is patentably distinct from Groups II, III, and V. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification with respect to Group I, restriction for examination purposes as indicated is proper.

Groups I, IV, VI, VII, and IX are related because the DNA of Group I encodes the receptor that is (1) interacting with the ligands used in the methods of treatment of Group IV, (2) being screened for using its epitopes in the methods of Group VI, (3) being acted on by the protease in the methods of Group VII, and (4) being assayed for ligands in the methods of Group IX. However, the DNA is not required to practice any of these methods since the receptor can be purified from natural sources and/or, with respect to the methods of treatment, the DNA is not in its isolated form as required for Group I. Thus, Group I is patentably distinct from Groups IV VI, VII, and IX. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification with respect to Group I, restriction for examination purposes as indicated is proper.

The DNA of Group I is related to the protein of Group VIII by virtue of the fact that the DNA encodes a full-length protein, a portion of which is claimed in Group VIII. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, they are distinct inventions because they are wholly different in structure and function. Moreover, the protein product can be made by other and materially distinct processes, such as purification from a natural source followed by protease degradation; and the DNA product can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, Groups I and VIII are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNA of Group I is related to the compositions (ligands) of Group X that affect bone strength or mineralization because the DNA encode the protein with which the ligands in the compositions interact. However, the DNA and the ligand compositions are distinct inventions because they are wholly different in structure and function. Moreover, they are not described as being useful together. Thus, Groups I and X are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups VIII and II-VII are related because the protein of Group VIII is the receptor that is (1) produced in the gene therapy methods of Group II, (2) produced for screening of ligands in Group III, (3) interacting with ligands in the methods of treatment of Group IV, (4) encoded by

the DNA used in the hybridization techniques of Group V, (5) is the cognate protein to the antibodies whose epitopes are used in the methods of screening in Group VI, and (6) acted on by the proteases of the methods of treatment of Group VII. However, the isolated protein is not required to practice any of these methods since the receptor is either (a) expressed by the DNA, never isolated, and assayed *in vivo* or (b) assayed *in vivo* directly. Thus, Group VIII is patentably distinct from Groups II-VII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification with respect to Group VIII, restriction for examination purposes as indicated is proper.

Groups VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the protein can be used in a materially different process of using that product, such as in the in vivo production of antibodies. Thus, Groups VIII and IX are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The protein of Group VIII is related to the ligand of Group X by virtue of the interaction between the protein and ligand (a specific association). Although the protein and ligand are related due to the necessary steric complementarity of the two, they are distinct inventions because they are structurally and functionally distinct chemical entities and because the proteins

can be used in processes materially distinct from the process to recognize ligands, such as in a receptor activity assays. Therefore, Groups VIII and X are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group X is related to Groups IV and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the peptide ligands of Group X can be used for a materially different process of using that product, such as being used as small molecular weight markers on a protein gel. Thus, Group X is patentably distinct from Groups IV and VII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (Group X from Group VII), restriction for examination purposes as indicated is proper. While Groups X and IV are identically classified, they require distinct searches based on the distinct method steps used.

Group X is related to Groups II, III, V, VI, and IX because the ligand of Group X binds the receptor that is (1) produced in the gene therapy methods of Group II, (2) produced for screening of ligands in Group III, (3) encoded by the DNA used in the hybridization techniques of Group V, (4) is the cognate protein to the antibodies whose epitopes are used in the methods of screening in Group VI, and (6) assayed for in the screening methods of Group IX. However,

the ligand is not required to practice any of these methods. Thus, Group X is patentably distinct from Groups II, III, V, VI, and IX. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification with respect to Group X, restriction for examination purposes as indicated is proper.

Groups II, III, and V are related as methods of using the DNA that encodes the BSMR protein. These Groups are distinct, however, due to their distinct methods steps and reagents to produce distinct products. For example, Group II uses gene therapy methods, such as infectious viruses, Group III uses DNA to express the BSMR protein for assaying ligands to said protein, and Group IV uses DNA in hybridization methods to identify the BSMR DNA in a patient. Each Group has a different result. Thus, Groups II, III and V are patentably distinct, each from the other. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (Group II from Groups III and V), restriction for examination purposes as indicated is proper. While Groups III and V are identically classified, they require distinct searches based on the distinct method steps used in each of the methods.

Groups IV and VII are related as methods of using the ligands that interacts the BSMR protein. These Groups are distinct, however, due to their distinct methods steps and reagents to produce distinct products. For example, Group IV uses the ligands only in methods of treatment and/or regulation while Group VII used the ligands and/or proteases to increase bone strength in a human. Thus, Groups IV and VII are patentably distinct. Because these inventions are distinct

for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups II, III, and V are related to Groups IV and VII are related to Group IX by virtue of the BSMR protein whose encoding DNA, ligands, or the protein itself are used in the methods. These groups of methods are distinct, each from the other, based on their distinct reagents and method steps to produce distinct results. Thus, Groups II, III, and V are patentably distinct from Groups IV and VII are patentably distinct from Group IX.

Notice of Possible Rejoinder

4. The Examiner notes that if product claims in Group listed below are found directed to an allowable product, then process claims in associated Groups listed below, which are directed to processes of making or using the patentable product, respectively, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Allowable Product Group	Possible Rejoinder Group(s)
I (DNA)	II, III, V
VIII (protein)	IX
X (ligand)	IV, VII

Election

5. A telephone call was made to Patricia Granados on July 18, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

6. A complete response to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
July 20, 2003